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Pascal E. Delrieu

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EXAMINER

FISHER, ABIGAIL L

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

10/20/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/017,259	DELRIEU ET AL.	
	Examiner	Art Unit	
	ABIGAIL FISHER	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-32,37-45,64 and 66-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-32,37-45,64 and 66-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 30 2010 has been entered.

Receipt of Amendments/Remarks filed August 30 2010 is acknowledged. Claims 1-18, 33-36, 46-63, 65 were/stand cancelled. Claims 19-20, 24, 30, 32, 37-38, 42 and 68-69 were amended. Claims 19-32, 37-45, 64 and 66-70 are pending.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejection of claims 32-35 under 35 U.S.C. 112, first paragraph, as failing to

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comply with the written description requirement is **maintained**.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification discloses chemicals, such as agar and polysaccharides, which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claim(s) 32 is(are) directed to encompass **synthetically modified polysaccharides, synthetically modified proteins and botanically derived gels**, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these synthetically modified polymers, synthetic polymers, natural polymers, and botanically derived gels, meet the written description provision of 35 USC § 112, first paragraph, due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. **Note: MPEP 2163.**

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of *the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Univ. of Rochester v. G.D. Searle, 69 USPQ2d 1886, 1892 (CAFC 2004), further supports this by stating that:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural

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term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

With the exception of the above specifically disclosed chemical structures, the skilled artisan cannot envision the detailed chemical structure of the encompassed synthetically modified polymers, synthetic polymers, natural polymers, and botanically derived gels, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The chemical structure itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016, (Fed. Cir. 1991). In Fiddes v. Baird, 30 USPQ2d 1481, 1483, (Bd. Pat. App. & Int. 1993), claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 (Fed. Cir. 1997) held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Furthermore, to the extent that a functional description can meet the requirement for an adequate written description, it can do so only in accordance with PTO guidelines stating that the requirement can be met by disclosing "sufficiently detailed, relevant identifying characteristics," including "functional characteristics when coupled with a known or disclosed correlation between function and structure." Univ. of Rochester v.

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G.D. Searle, 68 USPQ2d 1424, 1432 (DC WNY 2003).

Therefore, only the above chemically structurally defined chemicals, but not the full breadth of the claim(s) meet the written description provision of 35 USC § 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC § 112 is severable from its enablement provision. (See page 1115.)

Response to Arguments

Applicants argue that "synthetically modified polysaccharides", "synthetically modified proteins" and "botanically derived gel" do meet the written description. It is argued that one would know what chemical structures would meet these descriptions.

Applicants' arguments filed August 30 2010 have been fully considered but they are not persuasive.

While the specification provides the literal support for these polymers, the above rejection is not a new matter rejection. The claims are rejected under USC 35 112 first paragraph due to lacking chemical structural information for what they are and chemical structures are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. The specification only recites these genus but does not actually describe the polymers which are encompassed by the genus. The examiner disagrees that one of skill would know what chemical structures would meet the descriptions. One of ordinary skill could

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not immediately envision what structures would fall within these genres. Furthermore, they do not appear to be conventional terms (and therefore would not need to be described) as a search of these terms does not result in an art definition. One of ordinary skill would not be apprised of what constitutes "synthetically modified". Therefore, the rejection is maintained.

Modified Rejection Based on amendments in the reply filed on 8/30/10

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24, 32, 42, 68 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 as currently written is vague and indefinite. It is unclear what "botanically derived gel" are referring to. Applicants have provided no definition of botanically derived gels nor given any examples as what constitutes a botanically derived gel.

Response to Arguments

Applicants argue that gels and gelling agents are well known and manufacture of gelling agents are well known. Therefore it is argued that applicants do not need to recite what is commonly known in the art.

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Applicants' arguments filed August 30 2010 have been fully considered but they are not persuasive.

While the examiner agrees that Applicants are not required to recite what is well known, botanically derived gels do not appear to be well known. A search does not produce art which describes botanically derived gels. While gels and gelling agents are well known, the specifically recited gels do not appear to be. Therefore, the term is still deemed indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Modified Rejection Based on amendments in the reply filed on 12/16/09

Claims 19-32, 37-45, 64 and 66-70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bretz et al. (WO 98/04618, cited in the Office action mailed on 11/24/08) in view of Brandau et al. (US Patent No. 5183493, cited in the Office action mailed on 11/24/08), Grulke (Polymer Handbook, 1991, 519-524, 526-533, 544-550 and 557-559, cited in the Office action mailed on 11/24/08) and Hsiu et al. (Biochemistry, 1964).

Applicant Claims

Applicants claim a method of preparing a gel delivery system comprising gel particles said method comprising forming an aqueous solution of a polymer gelling agent said solution being maintained at a first temperature the solution being gellable at a lower temperature and the gelling agent having dispersed therein said at least one active agent and a restraining polymer and discharging the gelling agent solution through a discharge orifice into a moving stream of hydrophobic liquid aid hydrophobic

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liquid being at a second temperature below the gelling point of said gelling agent solution. The particles coalesce and the restraining polymer has sufficient molecular weight to prevent egress of the restraining polymer from the gel particle and wherein said restraining polymer is bonded to the at least one active agent also as to retain the active agent in the gel particles.

**Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)**

Bretz et al. (US Patent No. 6300468 is serving as the English translation of WO 98/04618 and all referred to column and lines are found in the US Patent) is directed to a process for producing porous polymer globules. The polymer beads are useful as catalyst carriers (abstract). The method as taught include dissolving the polymer at temperatures close to the boiling points of the solvents used, such as 100 to 180 °C (column 2, lines 27-40). Then the polymer solution is cooled either quickly or slowly (column 2, line 45). It is taught that it is with the scope of the invention to cool the hot polymer solution by introducing it in a known manner such as spraying or dividing it into droplets into a cooling medium such as cold or liquid air, solid carbon dioxide or liquid nitrogen (column 3, lines 25-30). It is taught that when selecting the solvent is it important to choose a solvent in which the polymer has high solubility at elevated temperatures and a low solubility at low temperatures so that as the temperature drops the polymer precipitate (column 2, lines 12-18). It is taught that the size of the polymer beads is affected by the way in which the polymer solution is cooled as well as the cooling times and aging temperature (column 2, lines 56-60). It is taught that if the hot polymer solution is sprayed, atomized or dived into droplets in a cooling medium

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mesobeads or macrobeads are obtained with an average diameter of 100 to 200 micrometers and 1000 to 5000 micrometers (1 to 5 mm) respectively (column 3, lines 7-11). It is taught that the polymer beads can be coated or impregnated with known additives such as additives with functional groups, complexing agents, surfactants, porosity affecting agents, etc. (column 3, lines 43-48). In examples, the beads are cooled at ambient temperature (25 °C) (example 1).

**Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)**

Bretz et al. do not teach that the solvent is water. However, this deficiency is cured by Grulke.

Grulke is directed to solubility parameter values. It is taught that the process of dissolving polymers in a solvent is governed by the free energy of mixing (page 519, section 1.1). Table 3.1 is directed to the solubility parameters of various solvents. Table 3.4 is directed to the solubility parameter ranges of commercial polymers.

Bretz et al. do not teach that the how the hot polymer solution is cooled other than indicating that it cooled in known manners for cooling such as dividing it into droplets. However, this deficiency is cured by Brandau et al.

Brandau et al. is directed to the manufacturing of spherical particles. The spherical particles are manufactured by generating droplets by means of a vibrating nozzles and solidification of the droplets so formed in a gaseous or liquid cooling medium (column 1, lines 6-11).The spherical particle size ranges from 5 micrometers to 5 millimeters (column 2, lines 15-20). It is taught that the cooling medium can be lateral to the droplets or in the same direction (column 3, lines 47-50). It is taught that

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the shape depends on the speed with which the droplets are solidified (column 2, lines 61-62). There is a supply container for the liquid phase, a feed line between supply container and nozzle head, a drop distance, a coolant supply unit and a collecting vessel for the spherical particles (column 4, lines 1-7). With the aid of gas pressure, the liquid phase is passed through the feed line to the nozzle head (column 5, lines 4-6). The use of different sized nozzle heads alters the weight of the resulting particle (column 5, lines 38-40). Exemplified diameters of the nozzle head are 350 micrometers (0.35 mm) and a flow rate of 7.2 ml/min (example 1). It is taught that adjustment of the drop distance adjusts the cooling time of the droplets and subsequently the shape (column 5, lines 58-61). It is exemplified that the microspheres were collected in a container and sieved (example 2).

While Bretz et al. teach that the polymer beads are useful as catalyst carriers, Bretz et al. do not teach that the catalyst is a polymer with active agent bonded to the polymer. However, this deficiency is cured by Hsiu et al.

Hsiu et al. is directed to alpha amylases as calcium metallo enzymes. It is taught that alpha-amylase possesses catalytic properties. It is taught that the structure is at least one g-atom of calcium per mole amylase in order for full activity. The calcium and amylase form a tight metal chelate structure (abstract)

***Finding of Prima Facie Obviousness Rationale and Motivation
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Bretz et al., Hsiu et al., Grulke and Brandau et al. and utilize alpha-amylase with calcium bound in the formation of polymer

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beads of Bretz et al. One of ordinary skill in the art would have been motivated to utilize alpha-amylase with calcium bound as Bretz et al. teach that the polymer beads can be utilized as catalyst carriers and Hsiu et al. teach that alpha-amylase is a catalyst. Therefore, one of ordinary skill in the art would have been motivated to place a known catalyst in a known catalyst carrier. It is noted that the instant claims do not limit active agent nor restraining polymer to a specific species. Since calcium is a known active agent it would read on the instantly claimed active agent and since Hsiu et al. teach that the metal chelate bond from the amylase serves to restrain the calcium. It would have been obvious to one of ordinary skill in the art to disperse the alpha-amylase prior to forming the beads as this provides an efficient synthesis which eliminates a method step and would cut down on manufacturing costs.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Bretz et al., Hsiu et al., Grulke and Brandau et al. and utilize water as the solvent. One of ordinary skill in the art would have been motivated to change the solvent utilized to solubilize the polymer based on the polymer. Bretz et al. teach that the solvent should have a boiling point from about 100 to 180 °C and chosen such that the polymer is soluble in the solvent at elevated temperature and not soluble at lower temperatures so it precipitates out of solution. Grulke teaches the solubility of commercially available polymer. It would have been obvious to one of ordinary skill in the to vary the polymer and subsequent solvent utilized and choose one that the polymer is soluble in only at high temperature in order to form spherical particles as taught by Bretz et al.

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It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Bretz et al., Hsiu et al., Grulke and Brandau et al. and utilize a dropping device such as that taught by Brandau et al. in order to form the spherical particles. One of ordinary skill in the art would have been motivated to utilize the dropping apparatus taught by Brandau et al. and Bretz et al. teach that the hot solution may be cooled in known manners such as dividing it into droplets into a cooling medium and Brandau et al. teach a dropping device for forming spherical particles.

Regarding the claimed flow rate, both Bretz et al. and Brandau et al. teach that the size of the beads and shape of the beads is controlled by the cooling time. It would have been obvious to one of ordinary skill in the art to vary the flow rate in order to optimize the size of the desired particles. It would have been obvious to one of ordinary skill in the art at the time of the invention to engage in routine experimentation to determine optimal or workable ranges that produce expected results. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. **In re Aller, 220 F. 2d 454, 105 USPQ 233 (CCPA 1955).**

Regarding the claimed temperatures, Bretz et al. teach dissolving the polymer at temperatures close to the boiling points of the solvents used, such as 100 to 180 °C. Therefore, the taught 100 reads on the instantly claimed 100. Furthermore, this temperature is something one of ordinary skill in the art would routinely optimize depending on the solvent utilized such that when a higher boiling point solvent is utilized

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a higher temperature would be required by when a lower boiling point solvent is utilized a lower temperature would be utilized. Bretz et al. additionally teach cooling at room temperature which is below the instantly claimed 30 °C.

Regarding the claimed “for topical application of at least one active agent”, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants argue that the combined references do not teach an aqueous solution containing a polymeric gelling agent, an active and a restraining polymer. Applicants argue that the combined references do not teach the active and restraining polymer entrapped in a gel particle during its formation.

Applicants’ arguments filed August 23 2010 have been fully considered but they are not persuasive.

While the examiner agrees that fundamental principle of chemistry teaches that like dissolve like, Bretz teaches a general idea of forming polymer beads entrapping catalyst active agents. Utilization of different polymers results in utilizing different

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solvents to dissolve the polymers. Grulke teaches the solubility of commercially available polymer. Therefore, when utilizing polymers that are polar it would have been obvious to utilize a polar solvent such as water. While Bretz may utilize non polar polymers and solvents, the idea would be equally applicable to polar polymers and polar solvents. Bretz teach forming a solution of polymer in solvent, heating it and then cooling it by known methods such as dividing it into droplets into a cooling medium. These are the methods steps claimed.

While Bretz teach impregnating the resulting polymer beads with catalyst, the resulting product would be the same. As argued above (in the body of the rejection), it would have been obvious to utilize the catalyst in the gelling solutions and then cool the heated solution to form beads that entrap the active as this is the final product taught by Bretz and this would allow for the elimination of method steps and cut down on manufacturing costs which would be beneficial to one of ordinary skill.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Abigail Fisher/

Examiner, Art Unit 1616